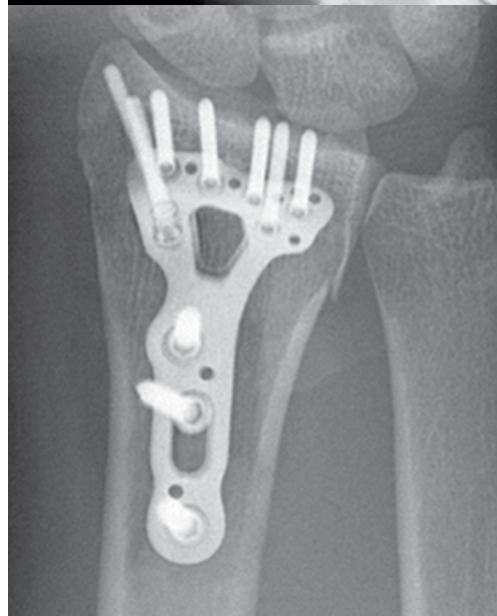


Value Analysis Committee Resource Guide



Acumed is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods, and approaches that improve patient care.




Acumed® Acu-Loc® 2

The original Acu-Loc Volar Distal Radius Plate has been a market leader in fracture fixation since its introduction in 2004. Acumed offered an innovative solution for repairing intra-articular fractures, malunions, and nonunions of the distal radius by designing the first anatomic volar plate.

In conjunction with our accomplished surgeon design team, Acumed developed the Acu-Loc 2 Volar Distal Radius (VDR) Plating System as the next generation in plating fixation. The system presents several new plate options, a two piece locking compression screw, instrumentation for fracture management, and new plate placement tools.

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Our mission is to aid the afflicted
through the ingenuity of our minds,
the labor of our hands, and the
compassion of our hearts.

About Acumed®

Acumed began as a family business in 1988 and evolved to become a market leader in developing innovative orthopaedic and medical solutions to improve patient care around the world. Acumed strives to advance the art and science of orthopaedics for the collective good and understands that innovation cannot come at the expense of value. Acumed blends knowledge, ingenuity, and skill to develop devices that solve real orthopaedic challenges to benefit the patient, surgeon, and hospital.

The company was founded as Accurate Machine and Design (Acumed) in an 1100-square-foot space in Butler, New Jersey, with a single machinist as the first employee. Accurate Machine and Design started out engineering prototypes for companies like Howmedica, Kirschner, and Exactech®, in addition to designing test machines and creating prototypes of hip stems, acetabular cups, and knee implants.

In 1991 the company relocated to Oregon as Acumed and launched the Oregon Fixation Screw. Intended for repair of ACL ligaments in the knee, the Oregon Fixation Screw was the first line of arthroscopy screws created by Acumed. The success of the product allowed Acumed to expand from the arthroscopy market into trauma. Acumed has continued to research, design, and manufacture products to improve patient care while adding new product lines each year, including Acutrak 2® Screws, Acu-Loc 2, Clavicle Plating System, Elbow Plating System, and the Fibula Rod System.

In 1999, The Marmon Group purchased Acumed. This allowed for investments in equipment and the purchase of a new building for additional on-site design and manufacturing. In 2002, after five decades of leading The Marmon Group as CEO, Robert Pritzker stepped down and created Colson Associates. This move allowed more time and attention to be focused on Colson businesses, including Acumed.

Today, Acumed is a multi-award-winning company dedicated to delivering innovative and quality medical device solutions. Committed to the highest standards of manufacturing, Acumed is proud to produce over 90% of our implants in the U.S.A., while 100% of our products are subject to rigorous quality control at our Oregon facility.

Throughout our history, Acumed has stayed true to our founders' vision of addressing the challenges facing orthopaedic surgeons and their patients. Acumed will continue to fulfill this vision by designing and developing innovative products and instruments to meet even the most complex indications and demanding procedural needs.

Acumed is headquartered in Hillsboro, Oregon, with a global distribution network and offices worldwide.

Dedicated to Excellence

From manufacturing to business practices to product innovation, Acumed has an unwavering commitment to excellence. It is reflected in the honors received from industry peers and in the performance of our suite of surgical fixation solutions.



THE AME MANUFACTURING EXCELLENCE AWARD

In 2011, Acumed received the AME Manufacturing Excellence Award, an honor recognizing North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission, and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain, and Lean Accounting.



THE FROST & SULLIVAN MANUFACTURING LEADERSHIP 100 OPERATIONAL EXCELLENCE AWARD

In 2013, Acumed received the Frost & Sullivan Manufacturing Leadership 100 award for Operational Excellence, an honor recognizing the top 100 global manufacturing companies who are shaping the future through projects that deliver outstanding value, innovation, and return on investment.

Frost & Sullivan Manufacturing Leadership 100 is the world's first member-driven leadership network with knowledge in manufacturing leadership. It was created through a global community of executives working within the manufacturing industry.

A LEADER IN PRODUCT DEVELOPMENT AND INNOVATION

Acumed began developing products for distal radius fractures in 1999. Since then, Acumed has grown to become one of the technology leaders in options for operative treatment of distal radius fractures.¹ Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advancing the field of orthopaedic surgery.

Acumed Maintains Ethical Behaviors with Respect to Compliance Standards and Laws.



INDUSTRY COMPLIANCE

As a logo member of the Advanced Medical Technology Association (AdvaMed), Acumed endorses the AdvaMed Code of Ethics. Adherence to this Code ensures ethical interaction with healthcare professionals. Acumed requires anti-corruption training for employees interacting with healthcare professionals or government officials (foreign or domestic). In addition, Acumed sales representatives in the United States as well as international distribution partners must complete anti-corruption training programs.

Acumed also supports the United Nations Global Compact and Boston College Center for Corporate Citizenship organizations.

TRANSPARENCY IN BUSINESS PRACTICE

In 2012, the company began preparing to track and report spending in accordance with the Physician Payment Sunshine Act. In order to become an Acumed partner, all distributors must go through a due diligence analysis and a robust training and education program to ensure they share Acumed's values with respect to anti-corruption and compliance. Acumed maintains ethical behaviors with respect to compliance standards and laws.



GREEN INITIATIVES

Acumed has formed a cross-functional group dedicated to preserving the environment and educating Acumed employees on the benefits of being "green". The Green Team's purpose statement is:

We empower Acumed and the global community through education, encouragement, and execution of sustainable business practices. By doing this, we engage our sphere of influence to deliver innovative products that respect the community's natural systems, support ethical equity, and drive customer loyalty.

The Acumed vision includes being respectful stewards of our local community and global environment, and a large part of this is our commitment to "green" initiatives.

No Bottled Water Pledge

The Green Team sponsored a "no bottled water" pledge program to reduce the consumption of bottled water by Acumed. To date, over 200 employees have pledged to avoid drinking bottled water while on site or traveling domestically on behalf of Acumed. In addition, during on site sales rep trainings, attendees are provided with reusable water bottles.

Papercut

Acumed is committed to reducing paper consumption in our daily business operations. The Green Team drove projects to reduce paper consumption and will expand this to reduce overall landfill waste. Activities include eliminating paper stubs, defaulting to double-sided printing, copying, and providing compostable lunchroom supplies.

The Facts on Distal Radius Fractures

According to the study, "Plating of the Distal Radius," that appeared in the Journal of the American Academy of Orthopaedic Surgeons, distal radius fractures make up as much as 15% of all extremity fractures.² Surgical fixation of unstable distal radius fractures continues to evolve in an effort to provide rigid stabilization, permit motion early, and reduce soft tissue morbidity.¹ Distal radius plates are the standard of care for these fractures, which are among the most common forms of skeletal injuries in the adult population.³ Distal radius fractures tend to be more common in the elderly because the bone becomes osteoporotic over time. Patients not only include elderly individuals, but also younger persons involved in high-energy trauma.

Historically, distal radius fractures have been treated by a variety of methods. Literature states that treatment options can range from closed reduction and immobilization to open reduction with plates and screws. The study also mentions that plating allows direct restoration of the anatomy, stable internal fixation, a decreased period of immobilization, and early return of wrist function.²

According to iData Research Inc., the distal radius device market was a 238.2 million dollar business in 2012 with a forecast of over 313 million by 2018. Also, in 2012 there were approximately 163,950 cases reported with a projection of 232,000 cases by 2018.³

CLASSIFICATION OF DISTAL RADIUS FRACTURES

The "Plating of the Distal Radius" study also states that conceptually, the distal radius and ulna may be divided into three columns based on the anatomy. This columnar classification can be used to guide treatment plans. The distal radius is divided into the lateral and medial columns, which anatomically correlate with the scaphoid facet and lunate facet, respectively. The medial column of the distal radius is further subdivided into dorsal medial and volar medial columns. The lateral, dorsal medial, and volar medial columns correspond with Melone's system for classifying intra-articular distal radius fractures. The ulnar column represents the ulnar styloid and the TFCC.²

There are multiple classifications for wrist fractures. The Universal classification system is descriptive but does not direct treatment. Universal codes include:⁴

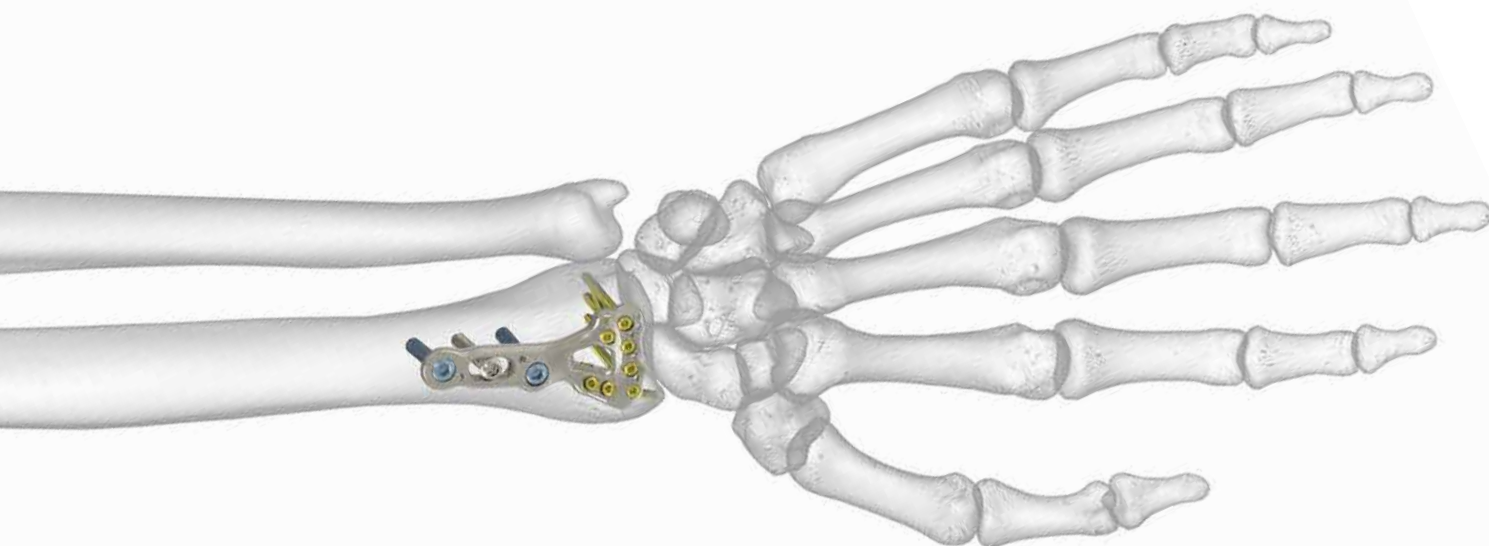
- Type I: extra-articular, undisplaced,
- Type II: extra-articular, displaced,
- Type III intra-articular, undisplaced
- Type IV: intra-articular, displaced

Studies show that the system that comes closest to directing treatment has been devised by Melone.⁴ This includes: I Stable fracture, II Unstable "die-punch", III "Spike" fracture, IV Split fracture, and V Explosion injuries. An anatomic description of the fracture may be the easiest way to describe the fracture, decide on treatment, and make an assessment of stability.⁴

Examples:

- Articular incongruity
- Radial shortening
- Radial angulation
- Comminution of the fracture (the amount of crumbling at the fracture site)
- Open (compound fracture) or closed injury
- Associated ulnar styloid fracture
- Associated soft tissue injuries

Distal Radius Fracture Treatment Options



SURGICAL VERSUS NON-SURGICAL INTERVENTION

A 2011 study, "Distal radius fractures treated with non-surgical treatment", concluded that the treatment of distal radius fractures should consider individualized treatment plans for every patient and for each type of fracture. Specific indications for surgical and non-surgical treatment should be taken into account to develop reasonable and viable treatment options.⁵

According to a published report in the Journal of Bone and Joint Surgery, the operative treatment of distal radial fractures has become increasingly common as compared with nonoperative treatment.⁶

*"Over the last fifteen years, there has been a trend toward internal plate-and-screw fixation for the treatment of these fractures"*⁶

SURGICAL INTERVENTION WITH PLATE FIXATION

History

In addition to splinting and casting, external fixators and pins were among the first methods used for distal radius fracture fixation. By the mid to late 1980's and early 1990's internal fixation with the use of more modern classification systems became increasingly common. Melone classification was first described in 1984 with the AO classification first being used in 1986.⁷

Recent studies have shown that internal fixation of unstable distal radial fractures with a volar locking plate system provides excellent outcomes. These results are associated with the prevention of radial shortening, malunion, and articular incongruity based on the stable fixation of Volar Locking Plate System.⁸ In 2010, the Acu-Loc 2 Volar Distal Radius (VDR) Plating System expanded to encompass the Volar Locking Plate, which feature 2.3 mm distal locking screws that target the radial styloid to provide fixation of radial styloid fragments.⁸

Anatomic, Precontoured Distal Radius Plates

The distal radius plates are anatomically precontoured which assists in restoring the original structure of the patient's anatomy with little or no bending of the plate. The design of the precontoured distal radius plates is meant to avoid the need to bend a plate intraoperatively, which could save time during the operative procedure. The Acumed Acu-Loc 2 is a comprehensive plating system for repairing intra-articular fractures, malunions and nonunions of the distal radius.

PLATE CONSTRUCTION

Another important consideration when choosing a plating system is its construction material. The elasticity of the plate material can impact the strength of the healing fracture. In order for the distal radius to heal properly the bone must be under constant load, thereby strengthening the newly formed bone during the healing process. Therefore, the plate must have enough elasticity to create stress on the healing distal radius while maintaining enough support and stabilization during the healing process.⁹

Each unique plate material has a distinct measure of elasticity. While surgical steel has traditionally been used due to its high strength, it has since been surpassed by titanium as the preferred option. Titanium offers strength characteristics and elasticity closer to that of natural bone. Titanium implants also have tissue tolerance due to the fact that the material is highly inert and insoluble in body fluids. In addition, there is a lower incidence of hypersensitivity compared to other biometals.¹⁰

Acumed has designed the Acu-Loc 2 Volar Distal Radius (VDR) Plating System utilizing titanium grade material. The grade of titanium utilized in the Acumed Acu-Loc 2 Volar Distal Radius (VDR) Plating System, the VDR plates, and Distal Radius Fragment Specific (DRFS) Plates have been developed with both nonlocking and locking screw options.

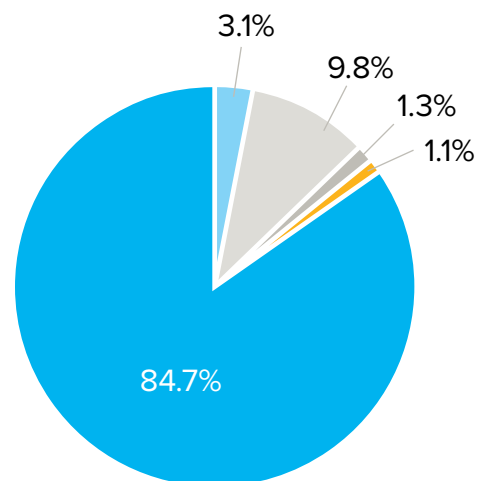


ACUMED® VDR PLATES CAN MEET USER/PATIENT NEEDS RESULTING FROM SEVERAL KEY FEATURES:⁹

- Anatomic fit allows the plates and screws to fit diverse patient population
- Low-profile plate design may reduce the chance for screw prominence above the plate
- Smooth and rounded plate edges may reduce patient soft tissue irritation
- Optimal plate strength aids in:
 - Maintaining thread position when screws are torqued into the plate
 - Bending
 - Compression loading

2013 Hand and Wrist Data

According to the 2013 US Market for Small Bone & Joint iData report, in 2012, the combined hand and wrist device market, which includes total wrist implants, wrist fusion plates, distal radius plates, ulnar head implants, and hand digit implants, exceeded \$281 million, a 4.7% increase over the previous year. Within the hand and wrist device market distal radius plates accounted for 84.7% of the total treatments.³



Continuing to Innovate in Plate Fixation

In 2004 Acumed introduced the Acu-Loc Volar Distal Radius Plate, the first anatomic volar plate for repairing articular fractures, malunions, and nonunions of the distal radius. While this plate continues to be a market leader, Acumed is pleased to have added the Acu-Loc 2 Volar Distal Radius (VDR) Plating System to the family of plating fixation options. Developed in conjunction with our accomplished surgeon design team, the system offers several new plate options, a two-piece locking compression screw, instrumentation for fracture management, and new plate placement tools.

Acumed® Product Solutions



Acu-Loc® 2 VDR Plates: Comprised of ten plates, these distally fitting silver plates offer coverage for complex intra-articular fractures.

Acu-Loc® 2 Proximal VDR Plates: This gold plate family includes ten plates and is designed for surgeons who prefer a more proximal plate placement. The Acu-Loc 2 Extension Plates can also be used with the proximal sitting plates. The Variable Angle Plating System, which can be used with all ten of the gold Proximal VDR Plates, includes two additional EX Plates from the original system. The Variable Angle Locking Screws allow for a variance of 5 mm dorsally.

Distal Radius Fragment Specific (DRFS) Plates: Six fragment specific plates are designed to independently address fractures of the intermediate and radial columns.

THE ACUMED® ADVANTAGE

Precontoured anatomic plate designs assist in restoring the original structure of the patient's anatomy with little to no bending of the plate, which could help save time during the operating procedure. The Acumed Acu-Loc 2 Wrist Plating System replicates the anatomic contours of the distal radius and can act as a template when reconstructing a malunion, nonunion, or a highly comminuted fracture to provide support and reduce the fracture.

The implants are machined from a commercially pure titanium alloy and offer elasticity closer to that of bone while reducing the propensity for stress shielding.¹¹ Wolff's law states that if loading on a particular bone increases, bone will remodel itself to become stronger to resist loading and if loading on a bone decreases, bone will become weaker.¹²

The advantage to having this many plate options is the ability to address multiple different fractures with coverage of the volar/dorsal radius & ulna, intra-articular fractures, and the surgeon will also have the option of using an intermediate or radial column approach.

The Acu-loc 2 system contains plate families from the original Acu-Loc Volar Distal Radius Plating System. Features and components include:

- Acu-Loc Dorsal Plate
- Acu-Loc EX Plate (aforementioned to be used with Variable Angle Screw)
- Acu-Loc VDU (Volar Distal Ulna) Plates
- The Acumed 2.3 mm Locking Variable Angle Screw, which can be used in any distal hole of the Acu-Loc 2 VDR Proximal Plates (gold) and Acu-Loc EX Plates (gold).
 - The screw allows a variance of 2.5 mm in any direction dorsally off of the fixed angle axis (at a 20 mm length.)
 - Orange color-coded instrumentation allows for quick identification of the proper drill, drill guide, and driver handle in the system.
- Optimized plate design allows for ideal support of the radial intermediate distal radius columns.
- Converging ulnar screws, new suture, and additional K-wire holes provide improved support of the volar ulnar lip and lunate facet.
- Plate window offers fracture visualization as well as access to metaphyseal comminution, utilizing the Fragment Reduction Tool for articular reconstruction.
- The Acumed Acu-Loc 2 VDR Plating System offers advanced instrumentation that may help with plate placement and fracture reduction.
 - Tools such as the plate positioning handle and radiolucent targeting guides with embedded radiopaque positioning posts help guide the surgeon during plate placement.
 - For support with corrective osteotomies, KickStand Posts aid in plate angulation relative to the dorsally displaced distal radius.
- Revolutionary Frag-Loc® two-piece locking fixation device provides compression between dorsal and volar fracture fragments through a small dorsal incision.
- The Acumed Acu-Loc 2 VDR Plating System features numerous different screw options which gives the surgeon a variety of screw types to accommodate the surgeon's preference for fracture fixation.
 - 2.3 mm bronze smooth locking pegs (8 mm–28 mm)
 - 2.3 mm gold fully threaded locking screws (8 mm–46 mm)
 - 2.3 mm silver non-toggling screws (8 mm–46 mm)
 - 2.3 mm locking variable angle screws (14 mm–28 mm)
 - 3.5 mm proximal locking screws (8 mm–18 mm)
 - 3.5 mm nonlocking screws (10 mm–18 mm)
 - 3.5 mm nonlocking hexalobe screws (10 mm–18 mm)
 - 3.5 mm locking hexalobe screws (8 mm–18 mm)

Associated Acumed® Products

- Acu-Loc® Volar Distal Radius Plating System
- Acu-Loc® Wrist Spanning Plate
- Acutrak® Headless Compression Screw—Mini and Standard
- Acutrak 2® Headless Compression Screw—Micro, Mini, and Standard
- ARC Wrist Tower System
- Forearm Fracture Solutions
- Hand Fracture System
- Modular Hand System
- SLIC Screw® System
- Small Bone External Fixation System
- Stableloc External Fixation System
- Total Wrist Fusion System
- Ulna Shortening Plating System

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510(k) Clearance Letters

K102998
Page 1 of 2

510(k) Summary

Device Trade Name:	Congruent Bone Plate System	JAN - 4 2011
Manufacturer:	Acumed, LLC 5885 NW Cornelius Pass Road Hillsboro, OR 97124	
Contact:	Mr. Ed Boehmer Global Regulatory and Quality Director Chief Compliance Officer Phone: (503) 627-9957	
Prepared by:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12 th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798	
Date Prepared:	December 14, 2010	
Classification:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories	
Class:	II	
Product Code:	HRS	

Indications For Use:

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

Device Description:

The predicate Congruent Bone Plate System (K012655) consists of bone plates and screws which provide fixation for fractures, fusions, and osteotomies of the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

The purpose of this 510(k) is to modify two components of the Congruent Bone Plate System and to add one component to this predicate system. These modifications are intended to allow the operating surgeon to better accommodate various patient anatomies when treating distal and midshaft fractures of the radius. All components are made of titanium alloy conforming to ASTM F136.

K102998
Page 2 of 2

Predicate Device:

The modified Congruent Bone Plate System is substantially equivalent to the predicate Congruent Bone Plate System previously cleared in K012655 with respect to indications, design, function, and materials.

Preclinical Testing:

The new components were subjected to static and dynamic 4-point bend testing in accordance with ASTM F382, Standard Specification and Test Method for Metallic Bone Plates. The results demonstrate that the modified components are substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Acumed, LLC
% Mr. Ed. Boehmer
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

JAN - 4 2011

Re: K102998

Trade/Device Name: Congruent Bone Plate System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS

Dated: October 6, 2010

Received: October 8, 2010

Dear Mr. Boehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

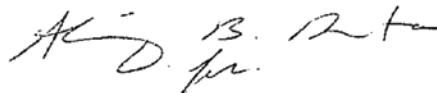
Page 2 – Mr. Ed. Boehmer

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102998

4. Indications for Use

JAN - 14 2011

510(k) Number (if known): K102998

Device Name: Congruent Bone Plate System

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off) for M. Melkerson
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102998

Page 1 of 1

K012655

NOV 07 2001

Appendix V - 510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

Classification Name: Plate, Fixation, Bone

Common Name: Bone Plate

Proprietary Name: Congruent Bone Plate System

Proposed Regulatory Class: II

Device Product Code: HRS

Manufacturing Facility: Acumed, Inc.

10950 SW 5th Street, Suite 170

Beaverton, OR 97005 U.S.A.

Establishment Registration No.: 3025141

Contact: Shari Jeffers

Labeling/Promotional Materials: See Appendix III

Substantial Equivalence:

The Acumed Congruent Bone Plate System is similar in indication, intended use, material, design, and size to Howmedica's Distal Humeral Plate (K890939) and Luhr Fixation System (K951415), to Synthes' Curved Reconstruction Plate (K011334), the Modular Foot System (K001941), and the One-Third Tubular Plate (K011335), and to Link's May Tibia Bone Plates (K912936). Literature on these predicate devices is included in Appendix IV.

The Congruent Bone Plate System consists of bone plates and screws for fractures, fusions, and osteotomies. The bone plates are pre-bent to minimize bending which is done intraoperatively. Instruments are supplied with the implants to aid in the insertion of the plates and screws. Each of the plate styles utilizes the same screw types and screw instruments for insertion. All of the plates and screws are manufactured from titanium and are provided non-sterile. The screws were cleared for marketing and distribution under K942340 and K942341.

Congruent Bone plates are provided non-sterile and are individually packaged in a plastic bag. On file at Acumed is data which shows that the instrumentation and implants can be successfully steam sterilized under specific process parameters which will obtain a resulting SAL of 10^{-6} . Information regarding labeling has been provided.

Predicate devices that are substantially equivalent to Acumed's Congruent Bone Plate System are Howmedica's Distal Humeral Plate and Luhr Fixation System; Synthes' Curved Reconstruction Plate, the Modular Foot System, and the One-Third Tubular Plate; and Link's May Tibia Bone Plates. All the devices mentioned above are manufactured from similar material, and have the same indication/intended use and similar design and size characteristics.

Based on the similarities between the Acumed Congruent Bone Plate System and the predicate devices studied, the safety and effectiveness of the Acumed Congruent Bone Plate System is expected to be similar to the predicate devices mentioned above.

10950 SW 5th Street, Suite 170, Beaverton, OR 97005 U.S.A. ♦ (503) 627-9957 ♦ Fax: (503) 520-9618

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 07 2001

Ms. Shari Jeffers
Manager of Regulatory Affairs
Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, Oregon 97005

Re: K012655

Trade/Device Name: Acumed Congruent Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 6, 2001
Received: August 13, 2001

Dear Ms. Jeffers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing


Page 2 – Ms. Shari Jeffers

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

NOV 07 2001

510(k) Number (if known): K012655

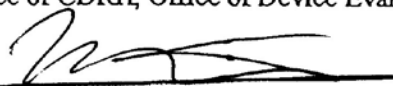
Device Name: Congruent Bone Plate System

Indications For Use:

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K012655

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

JUL 17 2012 12:38PM

NO. 7628 P. 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Acumed, LLC
% Ms. Brittany Cunningham
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124-9432

JUL 13 2012

Re: K120903

Trade/Device Name: Acumed Congruent Bone Plate System: 2.3 mm Variable Angle
Locking Screw for Use with Acu-Loc2 Plate

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and
accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: June 14, 2012

Received: June 15, 2012

Dear Ms. Cunningham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

JUL 17 2012 12:38PM

NO. 7628 P. 2

Page 2 – Ms. Brittany Cunningham

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

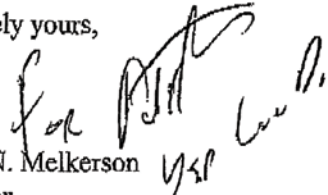
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUL. 17. 2012 12:38PM

NO. 7628 P. 3.

4. Indications for Use

510(k) Number (if known): K120903

Device Name: Acumed Congruent Bone Plate System

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120903



GEN10-03-B

Effective: **6/2014**

U.S. Patent No.

8,425,574

8,425,575

8,518,090

8,523,919

8,652,180

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